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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,684	10/25/2001	David P. Katz	AMBIINC.006A	3175

20995 7590 08/13/2004

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/001,684	KATZ, DAVID P.	
	Examiner	Art Unit	
	Patricia Leith	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *Please see "Addendum to Advisory" Attached hereto.*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-25*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Patricia Leith
Primary Examiner
Art Unit: 1654

ADDENDUM TO ADVISORY ACTION

The Request for reconsideration submitted after final rejection on 7/19/04 will be entered into the case. However, the Request does not place the claims in condition for allowance for the following reasons:

Applicant argues that the rejection made under 35 USC 112 First paragraph written description was made incorrectly and that although the Specification as filed does not explicitly teach exclusion of chromium yeast, that because the Specification teaches several other embodiments which include various chromium compounds; i.e., synthetic chromium compounds, that "the exclusion of other chromium-containing compounds that are not selected are inherently implied"

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'dmem., 738 F.2d 453 (Fed. Cir. 1984).

Because the disclosure recites that preferred embodiments include other embodiments which are positively recited, this rejection is hereby removed.

With regard to the rejection under 35 USC 103 over de la Harpe in view of Ostlund, Applicant argues that 'The Examiner has maintained the rejection of the claims based on an overly broad interpretation of the prior art. In '905, the effects of chromium depletion in laboratory rats is described to demonstrate the requirement of adequate dietary chromium in the function of insulin....As '905 does not discuss IR, its causes, or data from animals with normal dietary chromium intake, the Examiner's conclusion is not supported by the '905 reference.

However, to reiterate, de la Harpe et al. specifically taught that dietary supplementation of chromium to normal individuals had been linked to improvements in "glucose tolerance, serum lipid concentrations, including high density lipoprotein cholesterol, insulin and insulin binding..." To further reiterate, although de la Harpe et al. did not explicitly discuss IR, it is clearly implicitly disclosed as keenly described in previous office actions. Hence, Applicant's arguments are not persuasive.

Applicant further argues that "The Examiner stated in the latest Office Action that the administration of an agent which was known to alleviate insulin resistance "would have treated insulin resistance and thereby offered some beneficial treatment for PCOS or any disease whereby a symptom of the disease was insulin resistance" (p.4-

Arguments). Applicants further argue that "It appears that the Examiner considers IR to be an invariant symptom of PCOS and that by treating IR, other syndromes associated with PCOS would necessarily be treated. Disclosure in the present specification undermines both of these ideas. Paragraph [0009] describes a study.....but one fifth of the women demonstrated no insulin resistance....There is no motivation in the combined disclosures to use an agent for the treatment of IR in PCOS...Contrary to the position of the Examiner, IR and PCOS are not equivalent disorders" (pp.4-5 Arguments). However, Applicants seem to contradict themselves. Applicants clearly stated in a previous Amendment, rebutting a rejection that the Examiner had made under 35 USC 112 first paragraph that "...the hallmark features of PCOS include, inter alia, obesity, insulin resistance, and abnormal lipid profile. The present invention is based, in part, on the discovery that insulin sensitivity can play a significant role in the development of the various conditions associated with PCOS. For example, insulin resistance has been connected with hyperandrogenism....**By improving insulin sensitivity in an individual suffering from PCOS, symptoms associated with the disease will be reduced. This discussion in the specification is logical and consistent with scientific principals**" (emphasis added). Thus, it is concluded that the most recent argument has no basis, because Applicant previously stated the contrary in order to overcome the original rejection under 35 USC 112 First paragraph.

The rejections stand for the reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

07/27/04